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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,722	12/06/2001	Kei Roger Aoki	16952CON1DIV5CIP1	5741

7590 09/21/2004

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EXAMINER	
GUPTA, ANISH	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,722	AOKI ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Estoppel

§1.658 Final Decision:

> (c) A judgment in an interference settles all issues which (1) were raised and decided in the interference, (2) could have been properly raised and decided in the interference by a motion under §1.633 (a) through (d) and (f) through (j) or §1.634, and (3) could have been properly raised and decided in an additional interference with a motion under §1.633(e). A losing party who could have properly moved, but failed to move, under §1.633 or 1.634, shall be estopped to take ex parte or inter partes action in the Patent and Trademark Office after the interference which is inconsistent with that party's failure to properly move, except that a losing party shall not be estopped with respect to any claims which correspond, or properly could have corresponded, to a count as to which that party was awarded a favorable judgment.

1. Claims 1-16 are rejected on the grounds of estoppel under rule 37 CFR 1.658(c).

The claims are drawn to a method of treating mucus secretion of a patient using botulinum toxin and wherein the mucus secretion is not a symptom of rhinorrhea.

Applicants disagree that the subject matter of the present claims could have been presented during the interference. Applicants argue that Otitis media is associated with many symptoms, only one of which may be mucus secretion. Claim 5 of Sanders is directed to the treatment of otitis media, and is not directed to or even suggestive of reducing or treating any specific symptom of otitis media, let alone to treat mucus secretion. Further, the claims are not obvious over Sanders. Sanders fails to provide any disclosure, teaching, or suggestion, as to the type of symptom of otitis media that may be treated by trannstympanic administration of botulinum toxin. Importantly, Sanders does not even suggest that non-rhinorrhea mucus secretion can be treated using botulinum toxin..

Applicants augments, file 6-16-04, have been considered but have not been found persuasive.

The US Patent, in claim 5, states that the botulinum toxin was effective in the treatment of otis media. This claim is dependant upon claim 1. Claim 1 states that the toxin is administered to the cholinergic neurons for denervation, where denervation controls, amongst others, otitis media. It is well known in the art that mucus secretion is controlled by cholinergic nervous system (see Aoki et al. col. 8, lines 23-27). Furthermore, Nagaraj et al. teach that autonomic nervous system controls exist in the middle ear and control the pathogenesis of human middle ear effusion (see abstract). Thus, the treatment of mucus secretion in the middle ear was well within the scope of the claims given that Claim 1 specifies autonomic system and cholingeric nervous system. Accordingly, Claim 5 of the US Patent could have been the basis and additional count under 1.633(e)(1) and therefore Applicants are estopped.

The rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

2. Claims 1-16 rejected under 35 U.S.C. 102(g) as being anticipated by Sanders et al.

3. Claims 1-16 rejected under 35 U.S.C. 102(b) as being anticipated by Sanders et al. and Tos (HNO).

The claims are drawn to method of treating mucus secretion using botulinum toxin, wherein the mucus secretion is not a result of rhinorrhea.

For both rejections Applicants argue similar points and have these have been addressed below.

Applicants argue that the instant rejection is improper since Sanders et al. does not teach every element of the claimed invention. Further each and every element must be described in a single prior art reference. Since the rejection relies upon two references, the rejection under 102(b) is improper.

Furthermore, Sanders and Tos do not disclose or even suggest a method of administering botulinum toxin to a patient to reduce mucus secretion, which is not a symptom of rhinorrhea. Applicants argue that excessive mucus secretion is only one of many symptoms associated with otitis media. Other symptoms include pain, fever, hearing loss, sense of fullness in the ear, vomiting and tinnitus. Further, there are multiple types of otitis media. The general disclosure of treating otitis media, as set forth in Sanders, does not provide even a suggestion that mucus secretion of otitis media can be treated using the botulinum toxin. "Applicants submit that Sander's disclosure of a treatment of otitis media constitutes nothing more than speculation of potential treatment and is not a 'description' of the claimed invention within the meaning g of 35 U.S.C. 102."

Applicants augments, file 6-16-04, have been considered but have not been found persuasive.

First, Applicants are mistaken with their conclusions that multiple references cannot be used to anticipate the claims. Attention is directed to 2131.02 of the MPEP which states:

> "Normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:
> (A) Prove the primary reference contains an "enabled disclosure;"
> (B) Explain the meaning of a term used in the primary reference; or
> (C) Show that a characteristic not disclosed in the reference is inherent."

Here, the reference of TOS was cited to "show that a characteristic not disclosed in the reference is inherent." That is, that mucus secretion is a symptom of otitis media. Thus the use of multiple reference is certainly appropriate and well within the meaning 35 USC 102.

As for the actual teachings, Applicants state that mucus secretion is one of many any symptoms associated with otitis media. Other symptoms include pain, fever, hearing loss, sense of fullness in the ear, vomiting and tinnitus. Many of the these symptoms are a result of the cause of the infection, which is viruses or bacteria that infect the cells lining the eustachian tube, throat and middle ear. When infected, these cells become swollen and secrete a thick mucus which causes fluid and pressure to build behind the eardrum. Furthermore, given that claim 5 is dependant upon claim 1 in Sanders, one would conclude that otitis media with effusion is implied. Claim 5, states that the botulinum toxin was effective in the treatment of otitis media. This claim is dependant upon claim 1. Claim 1 states that the toxin is administered to the cholinergic neurons for denervation, where denervation controls, amongst others, otitis media. It is well known in the art that mucus secretion is controlled by cholinergic nervous system (see Aoki et al. col. 8, lines 23-27). Furthermore, Nagaraj et al. teach that autonomic nervous system controls exist in the middle ear and control the pathogenesis of human middle ear effusion (see abstract). Thus, the treatment of mucus secretion in the middle ear was well within the scope of the claims.

For these reasons, rejection is maintained.

4. Note that the references Aoki et al. and Nagaraj et al. have been cited to show the state of the art with respect to Otitis media and cholinergic secretion.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600